

Serial No.: 10/540,100
Group Art Unit No.: 4173

REMARKS

Status of Claims

Claims 1-12 are currently pending in the application; Claims 6 and 12 are withdrawn from consideration; Claims 1-5 and 7-11 are rejected.

Specification

The Examiner has noted that the incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper; accordingly, the Examiner requires Applicants to amend the disclosure to include the material incorporated by reference if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. Inasmuch as these materials are non-essential – Applicants are not relying on them to overcome any objection, rejection, or other requirement – no amendment is necessary.

Response to Rejection under 35 USC §112

Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. This rejection is rendered moot by the cancellation of this claim.

Response to Rejection under 35 USC §102

Claims 1-5 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Culshaw (US 2004/0138454 A1). This rejection is also rendered moot by the cancellation of these claims.

Response to Rejection under 35 USC §103

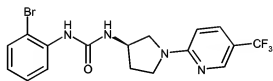
Claims 9-11 are rejected under 35 U.S.C. §103(a) as being unpatentable over Culshaw (US 2004/0138454 A1) further in view of Rami et al. (WO 03/022809). In response to this rejection,

Serial No.: 10/540,100
Group Art Unit No.: 4173

Applicants have canceled Claims 9-11 and added new Claims 13 and 14. Basis for Claim 13 can be found in canceled Claims 1 and 11; basis for Claim 14 can be found in the specification on page 26, 3rd paragraph, lines 1 and 2.

Rami et al. is art under 103(c), that is, it qualifies as prior art only under §102(c) because, at the time the claimed invention was made, it was owned by the same person or subject to an obligation of assignment to the same person. More particularly, Glaxo Group Ltd. and SmithKline Beecham plc were wholly owned subsidiaries of GlaxoSmithKline plc at the time the present invention was made. Accordingly, Rami et al. cannot be used to preclude patentability of the present application.

Culshaw by itself cannot be used to sustain a rejection since it does not teach or disclose Applicants' specifically claimed VR1 antagonist and, further, does not give a reason for a person of ordinary skill in the art to combine the specifically claimed VR-1 agonist, *N*-(2-Bromophenyl)-*N'*-[*((R)*-1-(5-trifluoromethyl-2-pyridyl)pyrrolidin-3-yl)]urea or a pharmaceutically acceptable salt thereof with rofecoxib or a pharmaceutically acceptable salt thereof. Indeed, Culshaw's disclosed VR-1 agonists, pyrido-pyrimidinones and pyrido-pyrimidindiones, are far afield from Applicants' VR-1 agonist (illustrated):



Accordingly, Claim 13 is patentable over Culshaw. Claim 14 which depends from Claim 13 and which necessarily includes all its limitations, is necessarily patentable.

In view of these amendments and remarks, Applicants respectfully request that the Examiner issue a Notice of Allowance for Claims 13 and 14. Should the Examiner have any questions or

Serial No.: 10/540,100
Group Art Unit No.: 4173

wish to discuss this application, the Examiner is encouraged to call Reid S. Willis at the number below.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read "Reid S. Willis", written in a cursive style.

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